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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,034	08/04/2000	Kwong Y. Tsang	A33081	2330

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/633,034	TSANG ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,22-41,43-45 and 47-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,22-41,43-45 and 47-54* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/04 has been entered.

2. Claims 1-15, 22-41, 43-45, 47-54 are pending.

Claims 1, 2, 4-8, 10-12, 22-25, 28-30, 33-34, 36-38, 41, 43-45, 47-49 have been amended and claims 51-54 have been added.

3. Claims 1-15, 22-41, 43-45, 47-54 are under examination.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

5. The following Office Action contains NEW GROUNDS of rejection.

6. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,688,657 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

7. Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

8. These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

9. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Oath/Declaration

10. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

11. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following: see above.

Rejections Withdrawn

12. The rejection of claims 1-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as indicated in part (a) of the previous office action is withdrawn in view of the amendments to the claims.

13. The rejection of claims 2-6, 17-29, 34-35, 38-41, 43, 47, 49-50 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the amendments to the claims, specification and the statements in the declaration of Dr. Arlen (filed with this response) and the statements in the response filed 8/26/03 stating that the hybridoma cell lines 33.26, Chi#1, and 31.1 will be irrevocably removed upon granting of a patent on this application (see page 7 of response of 8/26/03).

14. The rejection of claims 1, 7-16, 30-33, 42, 45-46, 48 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of amendments to the claims.

15. The rejection of claims 1, 8-9, 16 under 35 U.S.C. 102(b) as being anticipated by Herlyn et al (PNAS 76:1138, 3/79) is withdrawn in view of the amendments to the claims.

16. the rejection of claims 1, 8 under 35 U.S.C. 102(b) as being anticipated by Hollinshead et al (Cancer 56:480-489, 1985) is withdrawn in view of the amendments to the claims.

17. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Price et al (IRCS Journal of Medical Science 13:366-367, 1985) is withdrawn in view of the amendments to the claims.

18. The rejection of claims 16-21 under 35 U.S.C. 102(e) as being anticipated by Hopp et al (US Patent 4,703,004, filed 6/84) as evidenced by the specification is withdrawn in view of the amendments to the claims.

19. The rejection of claims 1, 7-23, 30-33, 36-37, 42, 44, 45, 46-49 under 35 U.S.C. 103(a) as being unpatentable over Hollinshead et al (Cancer 56:480-89, 1985) as applied to claims 1 and 8 above, and further in view of Neuberger et al (WO 86/01533, published 3/86) is withdrawn in view of the amendments to the claims.

20. The rejection of claims 1, 7-23, 30-33, 36-37, 42, 45, 46-49 under 35 U.S.C. 103(a) as being unpatentable over Herlyn et al (PNAS 76:1138, 1979) or Price et al (IRCS Journal of Medical Science 13:366, 1985) and further in view of Neuberger et al (WO 86/01533, published 3/86) is withdrawn in view of the amendments to the claims.

21. The rejection of claims 1-48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

22. The rejection of claims 2-6, 17-29, 34-41 under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought is withdrawn in view of the amendments to the claims.

23. The rejection of claims 2-6, 17-29, 34-41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

24. The rejection of claims 16-21, 46 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.

Response to Arguments

25. The rejection of claims 1-15, 22-41, 43-45, 47-54 rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251. See 37 CFR 1.175 is maintained because of the reasons set forth in paragraph 10 of this Office Action.

The following are NEW GROUNDS of Rejections

Claim Rejections - 35 USC § 101

26. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

27. Claims 2, 5, 6, 51, 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 2, 5, 6, 51, 53, as written, do not sufficiently distinguish over antibodies as they exists naturally because claims do not particularly point out any non-naturally occurring differences between the claimed antibodies and binding compositions and the structure of naturally occurring antibodies.

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" antibody or similar language would obviate this rejection.

Claim Rejections - 35 USC § 112

28. Claims 3, 6, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 3, 6, and 44 are indefinite for reciting molecular weights of proteins. In consideration of the discrepancies often encountered in the art between protein molecular weight when determined by different methods, when a molecular weight is recited to characterize a protein the claims should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were are used.

Claim Rejections - 35 USC § 102

29. Claims 5, 8-10, 13, 23, 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Herlyn et al (PNAS 76:1138, 3/79) and as evidenced by Koprowski et al (PNAS 74:2985-2988, 1977).

The claims recite an antibody which competitively inhibits the binding of the 31.1 antibody to the human colon carcinoma-associated protein antigen an the antibody is labeled with a cytotoxic radionuclide and is in combination with a carrier and an immunoassay for detection and an antibody which is raised against the antigen bound by the 31.1 antibody.

Herlyn et al teach antibodies to antigens from colon carcinoma cells and the antibody does not bind to normal cells and the antibody is radiolabled (see abstract and entire document) and as evidenced by Koprowski the label is 125I which is cytotoxic

(see Methods) and one would readily envisage that the antibody in the RIA is in a pharmaceutical carrier. Herlyn also teach radioimmunoassays for detection of colon carcinomas.

Claims 51-52 are directed to an antibody that is raised against the antigen that binds the 31.1 antibody. The method in which the antibodies were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

Herlyn is silent as to the characterization of the antigen but teaches the antigen is from colon carcinoma cells and does not bind to normal cells as characterized by the antigen in the instant application. Therefore, it is the Examiner's position that Herlyn et al have produced hybridomas which secrete antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Herlyn's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Herlyn have produced hybridomas that secrete antibodies that are identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed hybridoma and antibody with the hybridoma

and antibody of Herlyn, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 11/9/04 has been carefully considered but is deemed not to be persuasive. The response states that by amending the claims to be restricted to monoclonal antibodies 31.1 and their functional equivalents, the claims are novel over Herlyn (see page 16 of response). In response to this argument, the above rejection is made because the art of Herlyn et al still reads on antibodies that competitively inhibit binding of the 31.1 antibody.

30. Claims 5-6, 23, 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollinshead et al (Cancer 56:480-489, 1985).

Claims 5, 23, 51-52 have been described supra. Claim 6 recites wherein the antigen is about 72 kilodaltons.

Hollinshead et al teach monoclonal antibody to a colon carcinoma which induces an immune response (see page 481) and the antigen is not present in normal tissue (see page 487) and the antibody is used in an ELISA (see page 487) and the antigen is 72 kilodaltons (see page 481).

Claims 51-52 are directed to an antibody that is raised against the antigen that binds the 31.1 antibody. The method in which the antibodies were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

Hollinshead et al's antigen is described as being a colon carcinoma antigen which is not present in normal tissue and has a molecular weight of 72 kDa.

It is the Examiner's position that Hollinshead et al have produced hybridomas which secrete antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Hollinshead's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Hollinshead have produced hybridomas that secrete antibodies that are identical to the claimed antibody and bind the same antigen claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Hollinshead, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antibody of

the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 11/9/04 has been carefully considered but is deemed not to be persuasive. The response states that by amending the claims to be restricted to monoclonal antibodies 31.1 and their functional equivalents, the claims are novel over Hollinshead (see page 16 of response). In response to this argument, the above rejection is made because the art of Hollinshead et al still reads on antibodies that competitively inhibit binding of the 31.1 antibody.

31. Claims 5-15, 23, 30-33 , 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollinshead et al (Cancer 56:480-89, 1985) and further in view of Neuberger et al (WO 86/01533, published 3/86).

Claims 5-6, 23, 51-52 have been described supra. Claims 7-15, 30-33 recite wherein the antibody is on a solid phase, labeled with a cytotoxic drug or protein, compositions comprising such, kits comprising an antibody and a second detection antibody.

Hollinshead et al has been described supra. Hollinshead does not teach an antibody labeled with a cytotoxin, a kit comprising an antibody and a second antibody and a substrate for the enzyme. These deficiencies are made up for in the teaching of Neuberger et al.

Neuberger et al teach antibodies and antibodies that can be labeled with toxins, radiolabels, dyes, cytotoxic agents and ELISAs (see page 7) and the antibody can be immobilized for affinity chromatography (see page 8).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have labeled the antibody in view of Hollinshead et al and Neuberger et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have labeled the antibody in view of Hollinshead et al and Neuberger et al because Hollingshead et al teach the antigen is of molecular weight of 72 kD and the antigen is a colon carcinoma associated antigen and an ELISA for detection of the antigen in samples was performed and the antibody was labeled with an enzyme. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have labeled the antibody in view of Hollinshead et al and Neuberger et al because Neuberger et al teach labeling of antibodies for detection and treatment with cytotoxic agents and radiolabels of antibodies. Thus, it would have been obvious to one of ordinary skill in the art to produce an antibody which is a labeled antibody to the antigen of Hollinshead in view of Neuberger et al.

Although claims 30-33, recites a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the references read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and

methods of detectably labeling antibodies and derivatives thereof also were well known and available to the ordinarily skilled artisan.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Hollinshead et al's antigen is described as being a colon carcinoma antigen which is 72 kda and is not present in normal tissue. It is the Examiner's position that Hollinshead et al have produced hybridomas which secrete antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Hollinshead's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Hollinshead have produced hybridomas that secrete antibodies that are identical to the claimed antibody and bind the same antigen claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Hollinshead, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 11/9/04 has been carefully considered but is deemed not to be persuasive. The response states that by amending the claims to be restricted to monoclonal antibodies 31.1 and their functional equivalents, the claims are not obvious

over Hollinshead (see page 17 of response). In response to this argument, the above rejection is made because the art of Hollinshead et al still reads on antibodies that competitively inhibit binding of the 31.1 antibody.

32. Claims 5, 7-15, 23, 30-33 , 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herlyn et al (PNAS 76:1138, 1979) and as evidenced by Koprowski et al (PNAS 74:2985-2988, 1977) and further in view of Neuberger et al (WO 86/01533, published 3/86).

The claims have been described supra.

Herlyn et al have been described supra. Herlyn et al do not teach an antibody labeled with a cytotoxin, radiolabel, a kit comprising an antibody and a second antibody and a substrate for the enzyme. These deficiencies are made up for in the teaching of Neuberger et al.

Neuberger et al has been described supra.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have labeled the antibody in view of Herlyn et al in view of Neuberger et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have labeled the antibody of Herlyn et al in view of Neuberger et al because Herlyn et al teach a colon carcinoma antigen and detection of the antigen. In addition, one of ordinary skill in the art would have been motivated to

and had a reasonable expectation of success to have labeled the antibody of Herlyn et al in view of Neuberger et al because Neuberger et al teach labeling of antibodies for detection and treatment with cytotoxic agents and radiolabels. Thus, it would have been obvious to one of ordinary skill in the art to produce a antibody which is a labeled antibody to the antigen of Herlyn et al in view of Neuberger et al.

Although claims 30-33 recites a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the references read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detectably labeling antibodies and derivatives thereof also were well known and available to the ordinarily skilled artisan.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Herlyn is silent as to the purification characterization of the antigen but teaches the antigen is from colon carcinoma cells and does not bind to normal cells.

It is the Examiner's position that Herlyn have produced hybridomas which secrete antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Herlyn's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Herlyn have produced hybridomas that secrete antibodies that are identical to the claimed antibody and bind the same antigen. Since the Patent and Trademark Office does not have the facilities for examining and

comparing the claimed antibody with the antibody of Herlyn, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 11/9/04 has been carefully considered but is deemed not to be persuasive. The response states that by amending the claims to be restricted to monoclonal antibodies 31.1 and their functional equivalents, the claims are not obvious over Herlyn (see page 17 of response). In response to this argument, the above rejection is made because the art of Herlyn et al still reads on antibodies that competitively inhibit binding of the 31.1 antibody.

Conclusion

33. No claims are allowed.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

35. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832

LARRY R. HELMS, PH.D
PRIMARY EXAMINER